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Quality management — Guidelines for quality plans

Management de la qualité — Lignes directrices pour les plans qualité

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10005 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

Annexes A and B of this International Standard are for information only.

Introduction

This International Standard was prepared to address the need for a mechanism to relate generic requirements on quality system elements to the specific requirements of a particular product, project or contract. Its provisions should be considered advisory and not requirements.

A quality plan may be used within an organization to ensure that specific requirements for quality are being appropriately planned and addressed for identified products during production. A quality plan may be used to indicate the specific application of a quality system to a given development project, whether for a marketable product or for an in-house facility. A quality plan may also be used by the supplier in a contractual situation to demonstrate to the customer how the specific requirements for quality of a particular contract will be met. In many cases, it may be beneficial to obtain customer input to the development of the quality plan.

The quality plan should be compatible with other plans that may be prepared.

Quality management — Guidelines for quality plans

1 Scope

1.1 This International Standard provides guidelines to assist suppliers in the preparation, review, acceptance and revision of quality plans.

It is intended for use in two situations:

a) as guidance to a supplier organization in meeting the requirements of ISO 9001, ISO 9002 or ISO 9003 relative to the preparation of a quality plan; or

b) as guidance to a supplier organization in preparing a quality plan when the supplier does not have such a quality system.

In both situations, the quality plan is supplemental to the supplier's generic quality system documentation and should not duplicate the generic documentation. For convenience in situations of type b), this International Standard includes features that are covered in the generic requirements of ISO 9001, ISO 9002 and ISO 9003.

Quality plans provide a mechanism to tie specific requirements of the product, project or contract to existing generic quality system procedures. They do not require the development of a comprehensive set of procedures or instructions over and above those already existing, although some additional documented procedures may be necessary.

1.2 This International Standard is applicable where a quality plan is to be used for a particular product, project or contract. A quality plan may be applicable to any product of the generic product categories (hardware, software, processed materials and services) or industry/economic sectors.

A quality plan may be used to monitor and assess adherence to the requirements for quality, but these guidelines are not intended to be used as a checklist for compliance with requirements. A quality plan may also be used where a documented quality system does not exist, in which case procedures may need to be developed to support the quality plan.

NOTE 1 Annex B contains a bibliography of International Standards which provide information that may prove helpful to those involved in the preparation and review of quality plans.

2 Normative reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1994, *Quality management and quality assurance — Vocabulary*.

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 8402, together with the following definitions, apply. Terms which are repeated here for clarity but have been defined in other International Standards are identified by the placement of the number of the standard after the term being defined.

3.1 contract: Agreed requirements between a supplier and customer transmitted by any means.

[ISO 9001]

3.2 project: Unique process consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources.

NOTES

2 An individual project may form part of a larger project structure.

3 In some types of projects, the objectives are refined and the project characteristics defined progressively as the project proceeds.

4 The outcome of a project may be one or several units of a product.

3.3 type test: Test or series of tests directed towards approval of a design conducted to determine that it is capable of meeting the requirements of the product specification.

3.4 witness testing: Testing of a product in the presence of the customer's representative or a third party.

3.5 procedure: Specified way to perform an activity.

NOTES

5 In many cases, procedures are documented (e.g. quality system procedures).

6 When a procedure is to be documented, the term "written procedure" or "documented procedure" is frequently used.

7 A written or documented procedure usually contains the purpose and scope of an activity; what shall be done and by whom; when, where and how it shall be done; what materials, equipment and documents shall be used; and how it shall be controlled and recorded.

[ISO 8402]

3.6 product: Result of activities or processes.

NOTES

8 A product may include service, hardware, processed materials, software, or a combination thereof.

9 A product can be tangible (e.g. assemblies or processed materials) or intangible (e.g. knowledge or concepts), or a combination thereof.

10 A product can be either intended (e.g. offering to customers) or unintended (e.g. polluant or unwanted effects).

[ISO 8402]

3.7 quality plan: Document setting out the specific quality practices, resources and sequence of activities relevant to a particular product, project or contract.

NOTES

11 A quality plan usually makes reference to the parts of the quality manual applicable to the specific case.

12 Depending on the scope of the plan, a qualifier may be used, for example, "quality assurance plan", "quality management plan".

[ISO 8402]

3.8 quality system: Organizational structure, procedures, processes and resources needed to implement quality management.

NOTES

13 The quality system should be as comprehensive as needed to meet the quality objectives.

14 The quality system of an organization is designed primarily to satisfy the internal managerial needs of the organization. It is broader than the requirements of a particular customer who evaluates only the relevant part of the quality system.

15 For contractual or mandatory quality assessment purposes, demonstration of the implementation of identified quality system elements may be required.

[ISO 8402]

4 Preparation, review, acceptance and revision of the quality plan

4.1 Preparation

When preparing a quality plan, quality activities applicable to the situation should be defined and documented.

Much of the generic documentation needed may be contained in the supplier's quality manual and documented procedures. This documentation may need to be selected, adapted and/or supplemented. The quality plan shows how the supplier's generic documented procedures are related to and applied to any necessary additional procedures peculiar to the product, project or contract in order to attain specified quality objectives.

The quality plan should indicate, either directly or by reference to appropriate documented procedures or other documents, how the required activities are to be carried out.

The format and level of detail in the plan should be consistent with any agreed customer requirement, the supplier's method of operation and the complexity of the activities to be performed. The plan should be as brief as possible, consistent with meeting the provisions of this International Standard. (Simplified examples of alternative presentations of quality plans are contained in annex A.)

A quality plan may be a stand-alone document when a supplier does not have a documented quality system. A quality plan may also be included as part of another document or documents (e.g. product or project plan), depending on such things as customer requirements or the business practices of a specific supplier. It may be necessary to develop a quality plan that consists of a number of parts, each of which represents a plan for a distinct stage, such as for design, purchasing, production, or inspection and test, or for particular activities such as the dependability plan.

NOTE 16 When drafting a textural quality plan, the following conventions may be used:

— "shall" to express a provision that is binding between two or more parties;

— "will" to express a declaration of purpose or intent by one party;

— "should" to express a recommendation among other possibilities;

— "may" to indicate a course of action permissible within the limits of the quality plan.

4.2 Review and acceptance

The quality plan should be reviewed for adequacy and formally approved by an authorized group that includes representatives from all affected functions within the supplier's organization.

In contractual situations, a quality plan may be submitted to the customer by the supplier for review and acceptance, either as part of the precontract award-bidding process or after the contract has been awarded.

If the plan is submitted as part of the bidding process and a contract is subsequently awarded, the plan should be reviewed and, where appropriate, revised to reflect any changes in requirements that may have occurred as a result of precontract negotiations.

When a quality plan is required by a contract, it should normally be submitted prior to the start of the required activities. Where the contract is conducted in stages, the supplier should submit the quality plan for each stage to the customer prior to the start of that stage.

Procedures referenced in the plan should be made available to the customer, where agreed in the contract.

4.3 Revision

The supplier should revise the plan, when appropriate, to reflect changes that have been made to the product, project or contract, changes to the manner in which the product is produced or the service is provided, or changes in quality assurance practices.

Changes to the quality plan should be reviewed for impact and adequacy by the same authorized group which conducted the review of the original quality plan.

Subject to the specific requirements of a contract, proposed changes to the plan should be submitted to the customer for review and acceptance before they are implemented.

5 Contents of the quality plan

a) **Structure**

The contents of the quality plan should be based on this International Standard and the supplier's documented quality system. It is not essential that the quality plan follow the structure and numbering of any ISO 9000 standards and the alignment of the paragraphs in this International Standard is only intended to ease use and understanding.

The elements described in the following subclauses should be addressed, where relevant to the requirements of the product, project or contract.

b) **Scope of the quality plan**

The scope of the quality plan should be defined and should include, but not be limited to:

— the product or project to which it is to be applied;

— the scope of the contract to which it is to be applied;

— the product, project and or contract quality objectives (these quality objectives should be expressed in measurable terms wherever possible);

— specific exclusions;

— the conditions of its validity.

5.1 Management responsibilities

The plan should identify individuals within the supplier's organization who are responsible for:

a) ensuring that the activities required by the specified quality system or contract are planned, implemented and controlled and their progress monitored;

b) communicating requirements peculiar to the specific product, project or contract to all affected departments, subcontractors and customers, and resolving problems that arise at the interfaces between such groups;

c) reviewing the results of any audits conducted;

d) authorizing requests for exemption from quality system elements;

e) controlling corrective actions (see 5.14).

5.2 Quality plan and quality system

Much of the necessary quality plan documentation will normally exist as part of the quality system documentation. The quality plan need only refer to this documentation and show how it is to be applied to the specific situation in question. Where an element of such documentation does not already exist but is required, the quality plan should identify it and also identify when, how and by whom it will be prepared and approved.

5.3 Contract review

The plan should indicate when, how and by whom the requirements specified for the product, project or contract are to be reviewed.

The plan should also indicate how the results of this review are to be recorded and how conflicts or ambiguities in requirements are to be resolved.

5.4 Design control

The plan should indicate:

a) when, how and by whom the design process is to be carried out, controlled and documented;

b) the arrangements for the review, verification and validation of design output conformity to design input requirements;

c) where applicable, the extent to which the customer is to be involved in design activities, such as participation in design reviews and design verification.

The plan should reference applicable codes, standards, specifications and regulatory requirements, as appropriate.

5.5 Document and data control

The plan shoud indicate:

a) the documents and data applicable to the product, project or contract;

b) how such documents and data will be identified;

c) how, and from whom, access to such documents and data can be obtained;

d) how, and by whom, such documents and data are reviewed and approved.

5.6 Purchasing

The plan should indicate:

a) any important products that are to be purchased, from whom, and the relevant quality assurance requirements;

b) the methods to be used to evaluate, select and control subcontractors;

c) requirements for, and reference to, subcontractor quality plans, where appropriate;

d) the methods to be used to satisfy regulatory requirements which apply to purchased products.

5.7 Control of customer-supplied product

The plan should indicate:

a) how products provided by the customer (such as material, tooling, test equipment, software, data or services) are identified and controlled;

b) the methods to be used to verify that customer-supplied products meet specified requirements;

c) the methods to be used to deal with nonconforming products.

5.8 Product identification and traceability

Where traceability is a requirement, the plan should define its scope and extent, including how affected products are to be identified. Identification methods should also be considered when traceability is not required.

The plan should indicate:

a) how contractual and regulatory traceability requirements are identified and incorporated into working documents;

b) what records relating to such traceability requirements are to be generated and how they are to be controlled and distributed.

5.9 Process control

The plan should indicate how the production, installation and servicing processes will be controlled to ensure that specified requirements are met.

Where appropriate, the plan should include or reference but should not be limited to:

a) relevant documented procedures;

b) the process steps;

c) methods to be used to monitor and control processes and product characteristics;

d) acceptability criteria for workmanship;

e) use of qualified processes, associated equipment and personnel;

f) tools, techniques and methods to be used to achieve specified requirements.

Where installation is a requirement, the plan should indicate how the product will be installed and which characteristics have to be verified at that time.

5.10 Inspection and testing

The plan should indicate:

a) any relevant inspection and test plan (the items below may all be part of an inspection and test plan);

b) how the supplier will verify subcontractor product conformance to specified requirements;

c) where each inspection and test point is located in the process sequence;

d) what characteristics are to be inspected and tested at each point, the procedures and acceptance criteria to be used, and any special tools, techniques or personnel qualifications required;

e) where the customer has established points for witness or verification of selected characteristics of a product or its production and installation processes;

f) where inspections or tests are required to be witnessed or performed by regulatory authorities;

g) where, when and how the supplier intends, or is required by the customer or regulatory authorities, to use third parties to perform:

   1) type tests;

   2) witness testing (including on-site acceptance);

   3) product verification;

   4) product validation;

   5) material, product, process or personnel certification.

5.11 Control of inspection, measuring and test equipment

The plan should indicate the control system to be used for inspection, measuring and test equipment specifically intended for use for the product, project or contract, including:

a) identification of such equipment;

b) method of calibration;

c) method of indicating and recording calibration status;

d) what records of usage of such equipment are to be maintained so that the validity of previous results can be determined when such equipment is found to be out of calibration.

5.12 Inspection and test status

The plan should indicate any specific requirements and methods for the identification of the inspection and test status of products, documents and data.

5.13 Control of nonconforming product

The plan should indicate how nonconforming products are identified and controlled to prevent misuse until proper disposal.

Quality plans may need to define specific limitations, such as the degree or type of rework allowed.

The plan should address how and under what circumstances the supplier would request a concession for a product which does not meet specified requirements. In doing so, the plan should indicate:

a) who would have the responsibility to request such concessions;

b) how such a request would be made;

c) what information is to be provided and in what form;

d) who has been identified as having the responsibility and authoritiy to accept or reject such concessions.

5.14 Corrective and preventive action

The quality plan shoud indicate the preventive and corrective actions and follow-up activities that are specific to the product, project or contract in order to avoid the appearance or repetition of nonconformities. Those responsible for initiation and approval of corrective and preventive action should be identified.

5.15 Handling, storage, packaging, preservation and delivery

The plan should indicate:

a) how the specified requirements for handling, storage, packaging and delivery are to be met;

b) how the product will be delivered to the specified site in a manner that will ensure that its required characteristics are not degraded.

5.16 Control of quality records

The plan should indicate how records specific to the product, project or contract are to be controlled, including:

a) what records are to be kept, for how long, where and by whom;

b) what the legal or regulatory requirements are and how they are to be satistied;

c) what form the records will take (such as hard copy or electronic media);

d) how legibility, storage, retrievability, disposition and confidentiality requirements will be defined and satisfied;

e) what methods will be used to ensure that records are available when required;

f) what records are to be supplied to the customer, when and by what means;

g) in what language the records will be provided.

5.17 Quality audits

The plan should indicate the nature and extent of quality audits to be undertaken and how the results are to be used to correct and prevent recurrence of nonconformities which affect the product, project or contract.

Such audits may include:

a) internal audits by the supplier;

b) customer audits of the supplier;

c) supplier/customer audits of subcontractors;

d) third-party or regulatory authority audits of the supplier and subcontractors, including those carried out for quality system certification/registration purposes.

5.18 Training

The plan should address any specific training required for personnel carrying out a process that is a subject of the plan, and how such training is to be accomplished and recorded.

This should include:

a) training of new personnel;

b) training of existing personnel in new or revised operating methods.

5.19 Servicing

Where servicing is a specified requirement, the plan should indicate how the supplier intends to assure

conformance to applicable servicing requirements, such as:

a) regulatory and legislative requirements;

b) industry codes and practices;

c) service level agreements;

d) training of customer personnel;

e) availability of initial and on-going technical support during the agreed time period.

5.20 Statistical techniques

Where specific statistical techniques are required, they should be indicated in the plan.

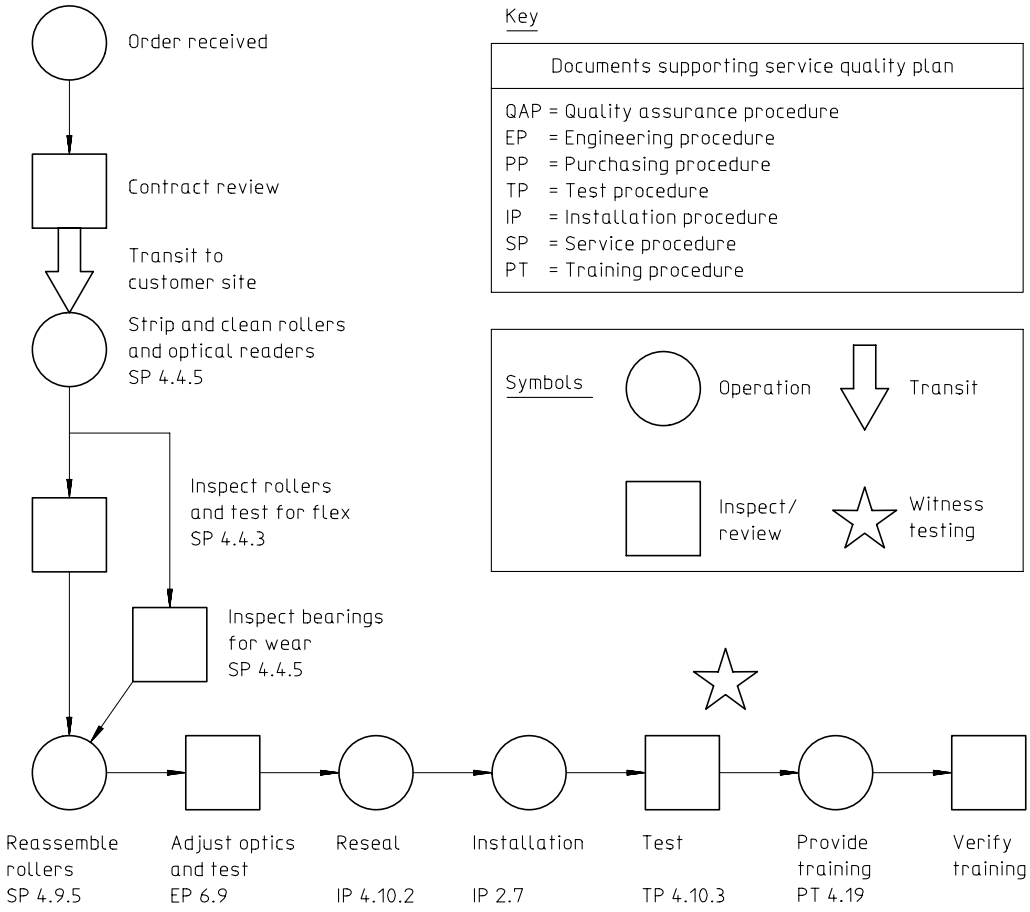
Annex A
(informative)

Simplified examples of formats for the presentation of quality plans

This annex provides examples of some of the ways in which quality plans may be presented. (See figures A.1 to A.4 and table A.1.)

The examples shown should not be taken as being complete as regards the quality plan content defined in clause 5 of this International Standard. Actual quality plans may be more complex. It would normally be expected that all of the elements would be covered, unless under some exceptional circumstance they do not apply to the case under review.

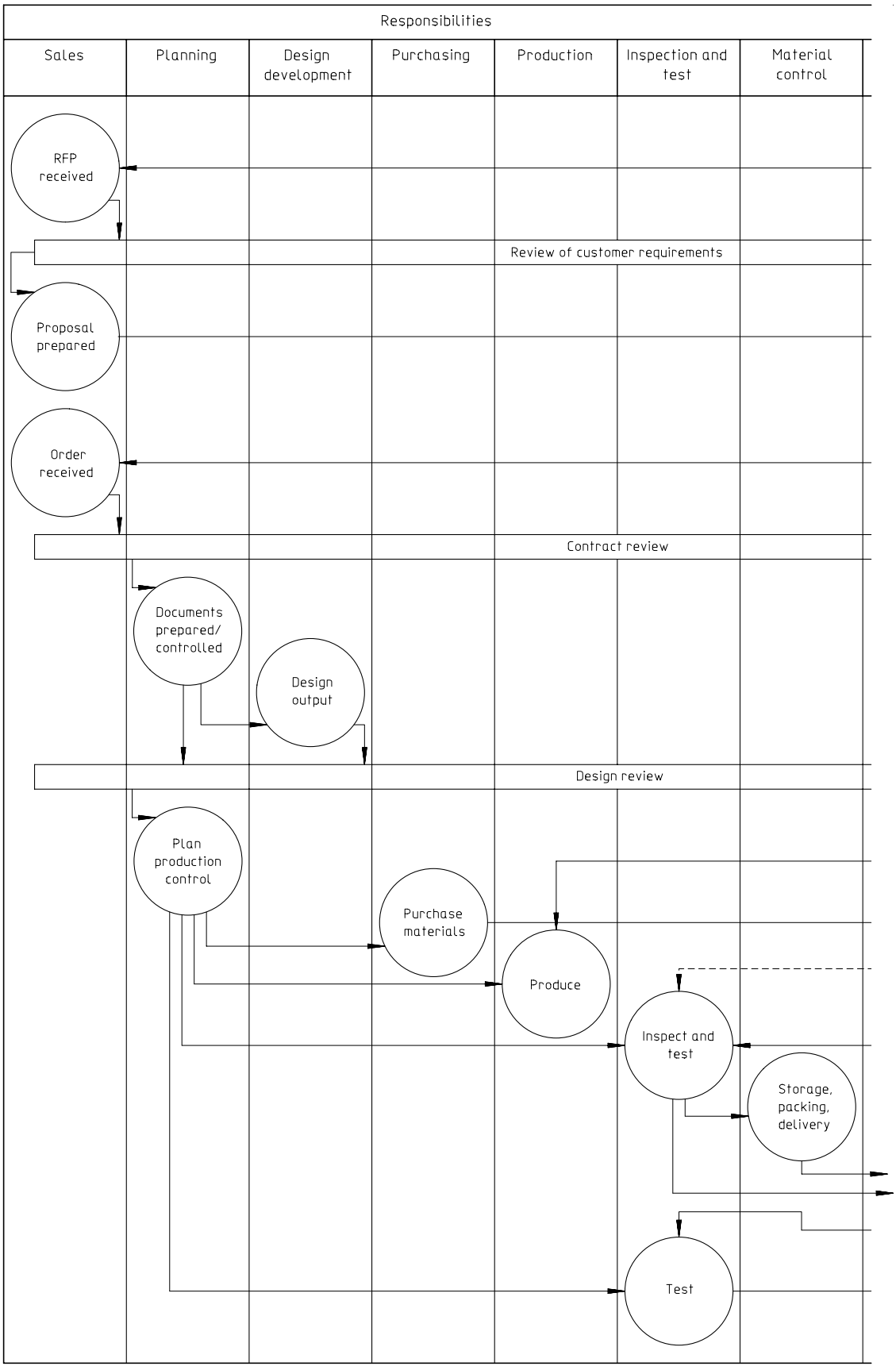
Presentation of quality plans can be in any form deemed suitable for meeting the agreed requirements. Even though the examples shown are in the form of flow diagrams, other forms better suited to a specific situation may be used. A textual presentation rather than a diagrammatic one may be more appropriate in certain circumstances. Similarly, a diagrammatic form may be supplemented with text.



NOTE — The service quality plan should also contain written descriptions and/or references to procedures or other documents for activities not shown on the flowchart, such as:

— document control,
— product traceability,
— third-party involvement,
— nonconformance,
— quality audits,
— quality records,
— management responsibilities.

Figure A.1 — Example of a format for a quality plan for services


Responsibilities
Sales
Planning
Design development
Purchasing
Production
Inspection and test
Material control
RFP received
Review of customer requirements
Proposal prepared
Order received
Contract review
Documents prepared/ controlled
Design output
Design review
Plan production control
Purchase materials
Produce
Inspect and test
Storage, packing, delivery
Test

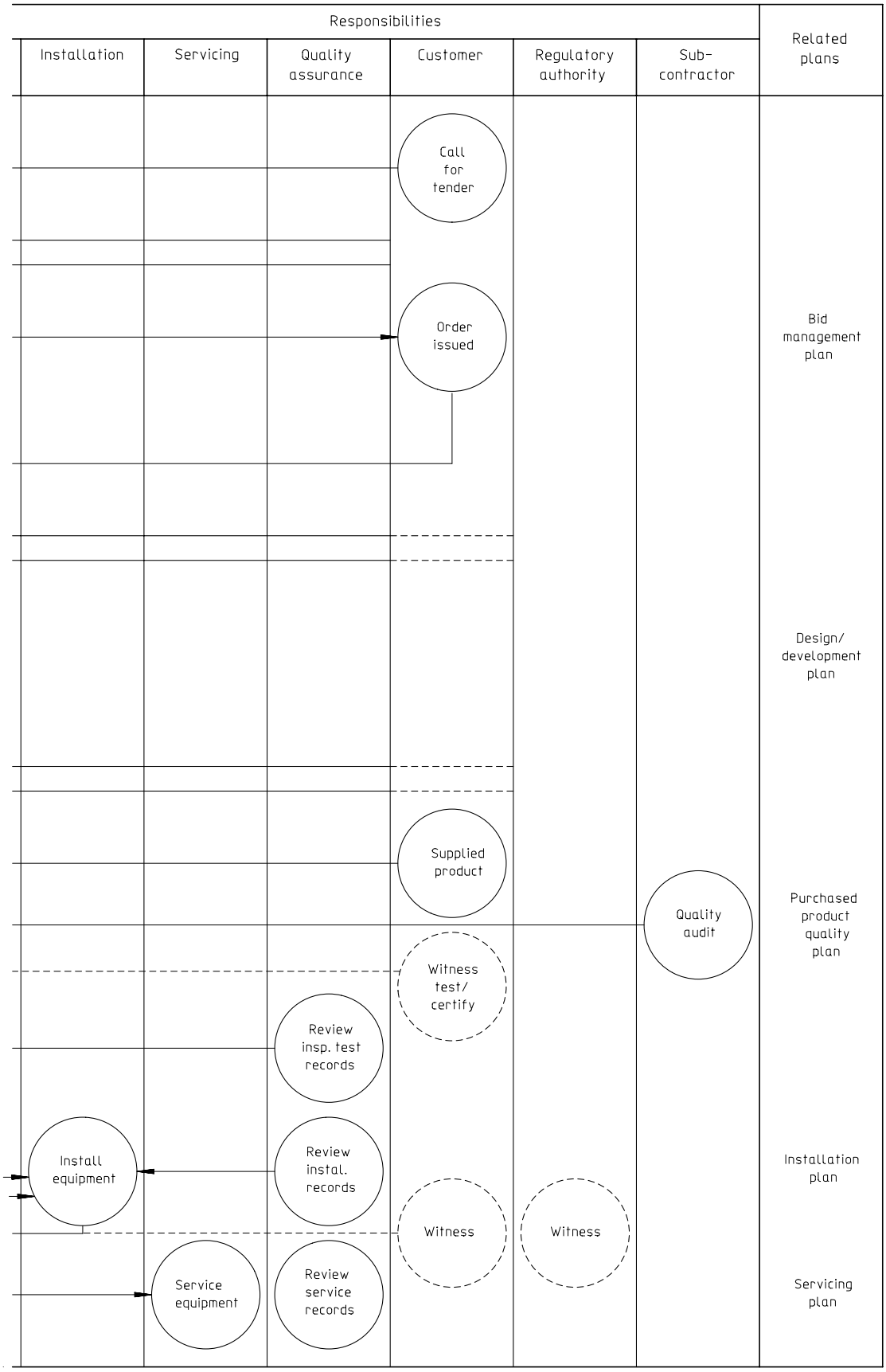


Figure A.2 — Example of a format for a quality plan for manufactured product

Part	Process flow chart [1]	Process stage	Work instruction number	Quality characteristic to be controlled (process condition to be checked)	Process control				Inspection	
					Instruction for process control number	Control method	Responsible function	Verification, instruction	Parameters	Procedure number
					IPC - 22		Workstation	VI - 29		
Part A		Preheating	WI - 123	Temperature		Check sheet Ref. No. 1	A			
		Forming	WI - 321	Temperature, pressure		Check sheet Ref. No. 2	B			
		Cutting		Length			C			
				Measure length		Control chart Ref. No. 1	D			
				Yield					Length	IT - 6

1) Symbols are as follows:

Manufacturing — Inspection and testing — Storage

Figure A.3 — Example of a format of a quality plan for a processed material

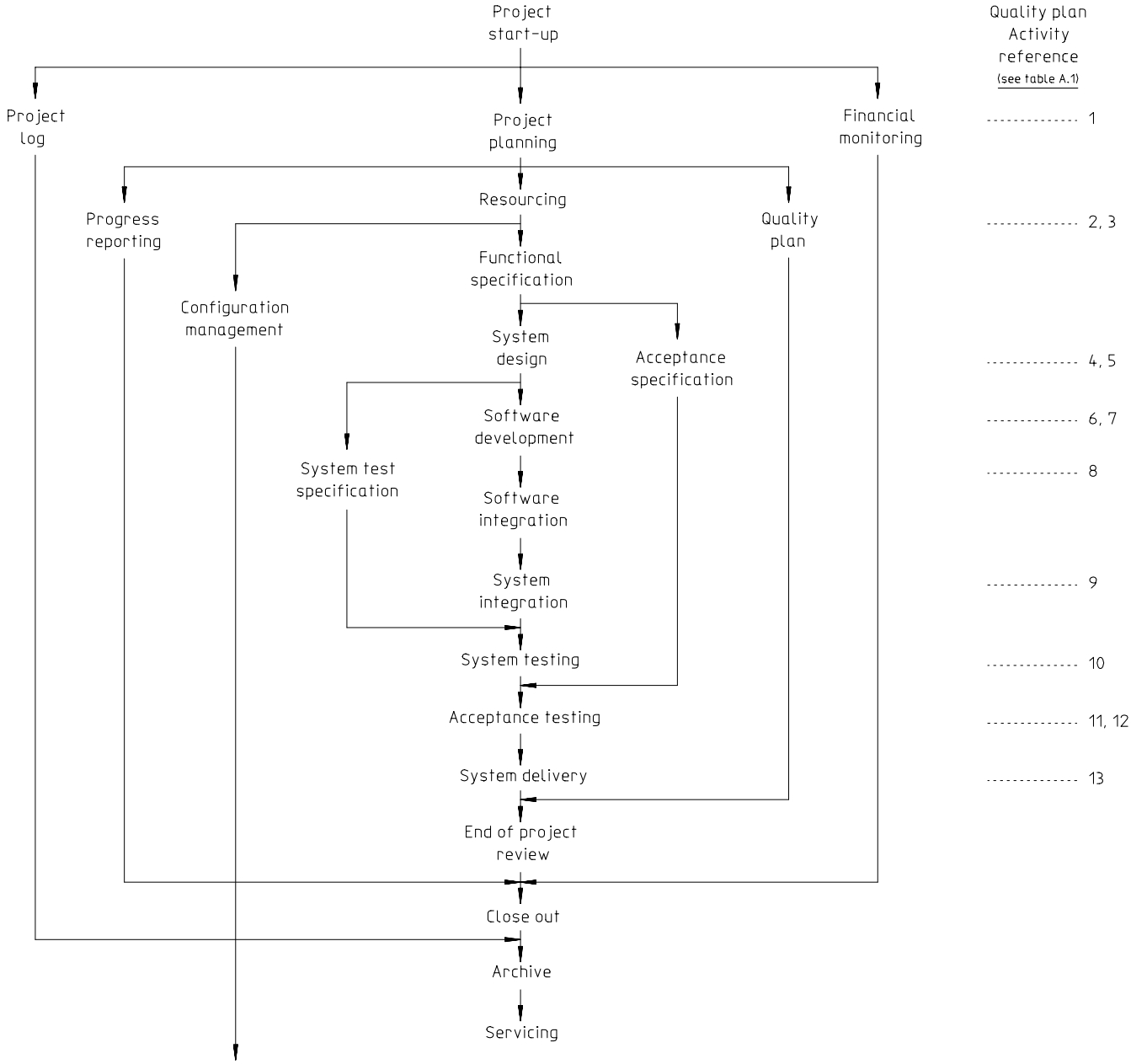


Figure A.4 — Simplified example of a software life cycle

Table A.1 — Software quality plan — Activity reference (see figure A.4)

Ref.	Activity description	Procedure	Comment	Assigned to	Approval authority
1	Contract review	QM 5.2	Contract M&P 1091	AMM	
2	Review plans	PMM 5.4		GT	
3	Requirements review	QM 5.3	Produce Doc. RS001	SME	
4	Design	PMM 5.6	Produce Doc. DS001	UT	
5	Design review	QM 5.6	Use expert review	SME	
6	Software implementation	SDM 5.6	Use C+ +		
7	Code review	QM 5.7	Use Fagan inspection		
8	Unit tests	SDM 5.7			
9	System integration	SDM 5.7			
10	System test	QM 5.7	Use customer data		
11	Clear nonconformances	QM 5.7			
12	User acceptance tests	QM 5.8	Client witnessing only		
13	Technical transfer	PMM 5.9			

Annex B
(informative)

Bibliography

[1] ISO 9000-1:1994, *Quality management and quality assurance standards — Part 1: Guidelines for selection and use*.

[2] ISO 9000-2:1993, *Quality management and quality assurance standards — Part 2: Generic guidelines for the application of ISO 9001, ISO 9002 and ISO 9003*.

[3] ISO 9000-3:1991, *Quality management and quality assurance standards — Part 3: Guidelines for the application of ISO 9001 to the development, supply and maintenance of software*.

[4] ISO 9000-4:1993, *Quality management and quality assurance standards — Part 4: Guide to dependability programme management*.

[5] ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

[6] ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing*.

[7] ISO 9003:1994, *Quality systems — Model for quality assurance in final inspection and test*.

[8] ISO 9004-1:1994, *Quality management and quality system elements — Part 1: Guidelines*.

[9] ISO 9004-2:1991, *Quality management and quality system elements — Part 2: Guidelines for services*.

[10] ISO 9004-3:1993, *Quality management and quality system elements — Part 3: Guidelines for processed materials*.

[11] ISO 10007:1995, *Quality management — Guidelines for configuration management*.

[12] ISO 10011-1:1990, *Guidelines for auditing quality systems — Part 1: Auditing*.

[13] ISO 10011-2:1991, *Guidelines for auditing quality systems — Part 2: Qualification criteria for quality systems auditors*.

[14] ISO 10011-3:1991, *Guidelines for auditing quality systems — Part 3: Management of audit programmes*.

[15] ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*.

[16] ISO 10013:1995, *Guidelines for developing quality manuals*.

[17] IEC 300-2:—[1)], *Dependability programme management — Part 2: Dependability programme elements and tasks*.

1) To be published.

ICS 03.120.10

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